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Ginger (Zingiber officinale) as anti-emetic prophylaxis for chemotherapy-induced nausea and vomiting

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 31/03/2020	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0236151198

Study information

Scientific Title

Ginger (Zingiber officinale) as anti-emetic prophylaxis for chemotherapy-induced nausea and vomiting

Study objectives
To establish the antiemetic efficacy of ginger (Zingiber officinale) in addition to standard antiemetic therapy for highly emetogenic cancer chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled open-label trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Nausea and vomiting

Interventions
A single supply of commercially available ginger capsules will be purchased. Patients in the study group will receive 550mg orally 3x a day for 5 days. 1st dose will be administered 1 hour prior to the first dose of chemotherapy. Trial medication will be used during the first cycle of chemotherapy only.

Study protocol: The study will recruit patients receiving FEC chemotherapy or any regimen containing cisplatin at 50mg/m2 or more in a single dose. Patients will be randomly and evenly allocated into 2 groups.
Group 1 - 59 patients receiving standard antiemetic therapy.
Group 2 - 59 patients receiving standard therapy plus ginger. Randomisation will be performed by the Clinical Trials Support Unit, Institute of Cancer Research.

Regimens: The chemotherapy unit at St George's Hospital has had a formal antiemetic policy in operation since 1998. Patients receiving FEC or cisplatin-based chemotherapy are routinely offered 'Level 4' antiemetic prophylaxis.

Schedule of clinical activity: Patients will be given a diary card to record nausea and episodes of vomiting for 5 days following administration of chemotherapy. Investigators will independently record episodes of nausea or vomiting on the Case Report Form. The use of salvage antiemetics will also be noted. Both nausea and vomiting will be graded according to the NCI common toxicity criteria.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ginger (Zingiber officinale)

Primary outcome(s)
Total antiemetic control (no nausea or vomiting during the study period)

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/05/2005

Eligibility

Key inclusion criteria
118 cancer patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Any prior chemotherapy
2. Anticipatory nausea/vomiting
3. Concurrent use of products containing ginger or ginger preparations
4. Concurrent use of any other experimental drugs
5. Clinical or radiological evidence of cerebral metastases
6. Clinical or radiological evidence of intestinal obstruction; any profound metabolic disturbance liable to cause nausea and vomiting (hypercalcaemia, diabetic ketoacidosis etc)
7. Any history of hypersensitivity to ginger
8. Any condition precluding the use of standard antiemetic therapy

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's Hospital
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St George's Healthcare NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration